EXHIBIT K

McCARTER &ENGLISH
ATTORNEYS AT LAW

April 19, 2010

VIA ECF

Hon. Ann Marie Donio, U.S.M.J.
United States District Court for the District of New Jersey
Mitchell H. Cohen Federal Building & U.S. Courthouse
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Re: ***AstraZeneca v. Apotex and AstraZeneca v. Breath***
Consolidated Civil Action No. 08 CV 01512 (RMB)(AMD)

Dear Judge Donio:

We write on behalf of plaintiffs AstraZeneca AB and AstraZeneca LP (collectively, "AstraZeneca") to review the state of fact discovery in advance of the April 29 status conference, and to respond to the issues raised by defendants Apotex, Inc. and Apotex Corp. (collectively, "Apotex") in their April 7, 2010 letter. (D.I. 147.) The issues that Apotex raised the afternoon before the previously-scheduled April 8 discovery conference with the Court are entirely without merit. Apotex ignores the facts, including the fact that its discovery requests were untimely. Apotex likewise ignores the law, including American case law establishing that U.S. privilege applies to AstraZeneca's withheld documents, and Swedish law, which if applicable, similarly defeats Apotex's request for production.

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Status of Fact Discovery

Fact discovery has now closed. All depositions, including those of third parties for which notices were issued, have been taken. Until Apotex's last-minute letter, the only matters pending before the Court were: (1) AstraZeneca's motion to compel Apotex to produce documents subject to its waiver of attorney-client privilege (D.I. 109); and (2) AstraZeneca's request that Apotex reimburse AstraZeneca for costs incurred as a result of Apotex's failure to meet discovery deadlines.[1] (D.I. 141.) With respect to the first of those issues, on April 7, AstraZeneca took the deposition of Bernice Tao – the witness through whom Apotex

[1] A third issue has recently arisen. During the April 1, 2010 deposition of Wan Jiang, Apotex's Rule 30(b)(6) corporate witness, Dr. Jiang described additional relevant documents which were not produced to AstraZeneca. At the deposition, AstraZeneca requested production, and has since sent two reminders. Yet, apparently, Apotex is still searching for these documents.

initially waived the privilege during the preliminary injunction hearing. Despite that waiver (and Apotex's repeated reliance on Ms. Tao's disclosure of advice that Apotex received from counsel), Apotex repeatedly instructed Ms. Tao not to answer questions directed to the same subject matter to which she previously testified. These instructions, in effect, rendered Ms. Tao's deposition a nullity.

Further, claim construction briefing closed at the end of last week, when the parties filed responsive *Markman* papers. Opening expert reports are currently scheduled to be exchanged on May 14.[2]

After more than a year of litigation, and the production of more than seven hundred thousand pages of responsive documents by AstraZeneca, it appeared last week as if this case might finally move forward to expert discovery. Then, remarkably, on the eve of the Court's scheduled April 8 status teleconference, Apotex filed a last-minute letter requesting that the Court delve back into fact discovery because, in Apotex's artful phrasing in the passive voice, "various issues have arisen" concerning AstraZeneca's discovery objections and privilege claims. (D.I. 147 at 1.) These new "issues" are mere gamesmanship. Apotex's letter, which includes 23 exhibits and more than 300 pages, misstates the facts and serves only to highlight Apotex's negligence in failing to pursue timely discovery.[3]

AstraZeneca served its initial discovery requests on Apotex on June 30, 2009. In contrast, Apotex waited to serve its ***first*** sets of document requests and interrogatories on AstraZeneca until January 8, 2010 – ***more than seven months*** after fact discovery commenced. Apotex's discovery requests demanded responses and production to be provided only days before the then-scheduled February 19 close of fact discovery, and after most of the depositions of AstraZeneca witnesses.

By the time that Apotex decided to engage in substantive discovery, AstraZeneca had been diligently searching for and producing documents in response to Breath's timely requests for ***more than seven months***. Notwithstanding the fact that Apotex made no document requests to AstraZeneca, beginning in July 2009, AstraZeneca produced to Apotex copies of documents that it produced to Breath. Indeed, in that month alone, AstraZeneca produced to Apotex about half a million

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[2] On April 15, 2010, the Court entered the parties' stipulated amendment to the case Scheduling Order, extending the expert discovery schedule by two weeks. (D.I. 169.)

[3] AstraZeneca was surprised by Apotex's letter to the Court. AstraZeneca had understood that Apotex's requests were no longer at issue, particularly in view of the fact that Apotex did request any conference with AstraZeneca to address its requests. *See* L.R. 37(a)(1).

pages that were produced in the previous *Ivax* case. AstraZeneca supplemented that production to both Breath and Apotex throughout 2009, in response to Breath's discovery requests. In doing so, AstraZeneca undertook significant expense and effort (including multiple overseas trips by counsel) to search for, collect, process and produce its documents well before the end of fact discovery in February 2010.

Throughout the entirety of 2009, while Apotex was reviewing AstraZeneca's documents, Apotex ***never*** once questioned, let alone complained about any alleged deficiencies in AstraZeneca's production. And, during extensive fact depositions conducted in January and February 2010, Apotex ***never*** once raised any of the alleged discovery deficiencies identified in its letter to the Court last week.

Apotex's delinquencies in this regard are no different from its delinquencies in providing discovery to AstraZeneca. As the Court will recall, Apotex confessed in December 2009 that it had neither collected nor produced any electronic documents in response to AstraZeneca's document requests. This necessitated two fact discovery extensions, and generated significant costs for AstraZeneca's counsel, who had to reschedule other client matters and cancel deposition and travel plans. These issues were detailed in AstraZeneca's March 10, 2010 letter to the Court. (D.I. 137.)

Only litigation tactics can explain why Apotex spent the better part of a year waiting to provide discovery, and, now, to also seek discovery of allegedly "highly relevant" information, and the intervention of the Court. Apotex's tactics not only threaten to significantly delay the case, but, as explained below, they lack substantive merit.

AstraZeneca's Discovery Objections Concerning Labeling Are Proper

AstraZeneca contends that Apotex's proposed generic version of PULMICORT RESPULES®, a nebulizable budesonide inhalation suspension ("BIS") product, will infringe the claims of AstraZeneca's patents-in-suit. Such patents include U.S. Patent Nos. 6,598,603 (the "'603 patent") and 6,899,099 (the "'099 patent"), which are directed to kits and methods for treating respiratory diseases by the administration of nebulized budesonide compositions in a continuing regimen of "not more than once per day." Apotex portrays Interrogatory No. 11 and Document Request Nos. 14-16 as "directly tailored" and "narrowly relevant" to a "central issue" that "goes to the very heart of this case." (D.I. 148 at 14-15; D.I. 150 at 13-15.) But Apotex's explanation of these allegedly vital requests, which took seven months to serve, is wrong.

1. Apotex's Interrogatory No. 11

Apotex Interrogatory No. 11 requests

> [f]or each country in which a nebulizable BIS [budesonide inhalation suspension] Product has been sold by or on behalf of Plaintiffs, identify (i) whether any instructions to titrate down to the lowest effective dose accompanied any sale of that product prior to December 31, 1997, and (ii) the specific language of those instructions. (D.I. 147 at 2.)

As an initial matter, this interrogatory, like Apotex's other discovery requests, seeks information that Apotex has refused to produce to AstraZeneca, *i.e.*, discovery concerning products other than those specifically at issue in this litigation. For example, in response to AstraZeneca's First Set of Requests for the Production of Documents and Things, Apotex repeatedly objected to discovery concerning its BIS products by stating that "Apotex further objects to this request to the extent that it is not limited to the product described in Apotex's ANDA No. 78-202."[4] Likewise, in its responses to AstraZeneca's First Set of Requests for Admission, Apotex even claimed that the term "Apotex's BIS," referring to Apotex's budesonide inhalation suspension, was "vague and indefinite."[5] Thus, Apotex refused to produce any documents other than those relating to the specific United States BIS product at issue in this case. For both AstraZeneca and Apotex, that product is AstraZeneca's PULMICORT RESPULES®. Apotex has sought and obtained FDA approval to market a generic version of PULMICORT RESPULES®. There are ***no*** foreign products involved in this case at all. Apotex's unilateral demand of foreign discovery should be denied.

Beyond that, Apotex dismisses AstraZeneca's substantive response to this interrogatory as "providing no information." (D.I. 147 at 2.) As even a cursory glance at AstraZeneca's response shows, however, AstraZeneca confirmed that it "did not sell a nebulized BIS product in the United States prior to December 31, 1997 that was accompanied by an instruction to titrate down to the lowest effective dose." (D.I. 148 at 15.) And, as AstraZeneca has explained to Apotex in correspondence (including citations to AstraZeneca's FDA submissions),

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[4] Ex. A, Apotex's Objections And Responses to AstraZeneca's First Set of Requests for the Production of Documents and Things (Nos. 1-61), dated August 17, 2009, at 7-25, 32, 36 and 44.

[5] Ex. B, Apotex's Objections and Responses to AstraZeneca's First Set of Requests for Admission to Apotex (Nos. 1-88), dated August 17, 2009, at 4-5.

AstraZeneca BIS products sold overseas prior to December 31, 1997 were all approved for ***twice-daily*** administration. (D.I. 149 at 2.) These products were unaccompanied by instructions indicating, whether explicitly or implicitly, that such products could be administered to a patient once daily. (D.I. 148 at 14.) There is simply no basis for assuming that the instructions for foreign BIS products are relevant to the asserted claims of the patents-in-suit. And, it is inconceivable that anyone before December 31, 1997 would have understood such language as relevant to once-daily administration.

Moreover, even if the information that Apotex now seeks is relevant to the case, its marginal relevance is far outweighed by the burden to AstraZeneca of having to go back and search AstraZeneca's files for responsive documents, and then collect, process and produce such documents. This burden is significant. As AstraZeneca explained to Apotex, by December 31, 1997, its BIS products had been sold in over ***thirty*** foreign countries. (D.I. 149 at 2.) As AstraZeneca also explained, AstraZeneca does not archive such dated product labels in a centralized database. (D.I. 152-1 at 3.) Apotex's request would, therefore, require AstraZeneca to search for information from dozens of countries for documents that may be decades old. Apotex's demands are excessively burdensome. *See Pub. Serv. Enter. Group Inc. v. Phila. Elec. Co.*, 30 F.R.D. 543, 551-52 (D.N.J. 1990). Moreover, Apotex's arguments suggest that it believes these labels to be public prior art. If this is so, then it makes little sense to require AstraZeneca to undertake Herculean efforts to find these documents.[6] Instead, Apotex should have collected these documents from public sources, rather than unfairly shifting the collection burden to AstraZeneca.

2. Document Request Nos. 14-16

Apotex's Document Request Nos. 14-16 seek the first government-approved label and/or package insert for, and the first or any revised versions of a label and/or package insert accompanying,

> [the] products known as Pulmicort, Pulmicort Respules, Pulmicort Turbuhaler, Pulmicort pMDI, Rhinocort, Rhinocort Aqua, Rhinocort Turbohaler, Rhinocort pMDI, Spirocort, Spirocort Aqua, Spirocort Turbohaler, Spirocort Nebu, Budamax, Pulmicort Nebuamp, Pulmicort Turbuhaler, Rhinocort Turbuhaler, Rhinosol, Aircort, Nebuhaler, and any product having the same formulations as any of the products

[6] This is especially true given that AstraZeneca would have produced such documents found in its files during previous searches.

> bearing these trade names, in each country for which the product has been sold. (D.I. 150 at 13-15.)

This exhaustive litany is inconsistent with Apotex's claim that these Document Requests are focused on "very specific" documents. (D.I. 147 at 3.) In fact, Apotex seeks documents on over ***nineteen*** budesonide products sold by AstraZeneca all over the world. For the same reasons discussed above in connection with Apotex's Interrogatory No. 11, there is no basis to assume that these labels and/or package inserts are relevant to the claims of the patent-in-suit. Contrary to the suggestion in Apotex's letter to the Court, Apotex has ***never*** explained to AstraZeneca why these requests are relevant. Instead, Apotex has ignored AstraZeneca's substantive objections, and made only conclusory assertions that the requested labels are "relevant to at least Apotex's invalidity contentions." (D.I. 152 at 3.) But that cannot be. This request is not limited to seeking documents before the filing date of the '603 and '099 patents. Apotex's gloss is plainly insufficient to warrant the burdensome production that Apotex seeks.

Moreover, as explained above, Apotex's Document Requests contradict positions that Apotex took throughout fact discovery, when it argued that products other than its specific generic version of PULMICORT RESPULES® was irrelevant to this case. For example, in response to AstraZeneca's First Set Of Document Requests, Apotex objected to "AstraZeneca's definition of 'Budesonide inhalation product' as vague, ambiguous, overly broad, and unduly burdensome to the extent that it includes any 'product developed, under development, considered for development, marketed or sold by Apotex, or anyone else, that includes budesonide as an active ingredient and is administered by inhalation.'"[7] Apotex should not now be permitted to change its position on the relevance of other products to launch an evidentiary fishing expedition.

AstraZeneca's Discovery Objections Concerning Prior Product Sales Are Valid

1. Interrogatory No. 16

Apotex's Interrogatory No. 16 requests:

> For each country in which a product containing budesonide has been sold by or on behalf of Plaintiffs prior to November 14, 1997, identify the date on which a sterile version of that product was first sold. (D.I. 148 at 17.)

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[7] Ex. A at 5.

In a March 9, 2010 letter to counsel for AstraZeneca, Apotex justified Interrogatory No. 16 with puzzling logic: "[s]ales of such products ***implies*** [*sic*, imply] the existence of publications regarding the same, and is [*sic*, are] therefore relevant to the validity of [United States Patent 7,524,834] (the "'834 patent")." (D.I. 148-1 at 2.) This is nonsense. As Apotex knows full well, foreign sales are irrelevant to validity under the patent statute, which limits prior art to inventions "patented or described in a printed publication in this or a foreign country ***or in public use or on sale in this country***, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b)[8]. Apotex's interrogatory is not directed to publications – real or implied – but rather to sales information. Even now, Apotex insists to the Court that AstraZeneca's overseas sales "are directly relevant to the invalidity of Plaintiffs' sterilization patent." (D.I. 147 at 4.) With respect to U.S. sales, AstraZeneca has already confirmed that "it has not sold any sterile inhalation product prior to November 14, 1997." (D.I. 149 at 3.) Further, the only sterile budesonide product sold outside the U.S. prior to that date was a cream for topical administration (Preferid®). As discussed below in connection with Document Request Nos. 43 and 44, discovery concerning that product is both irrelevant and would be incredibly burdensome to locate, if it could be located at all. And, there is no basis to assume the existence of any of the foreign publications sought, or, if they do exist, that they would be relevant as prior art publications to the claims at issue in this case.

In addition to not being "directly relevant", Apotex's Interrogatory No. 16 is not "narrowly tailored." (D.I. 148 at 17.) It requests foreign sales information on "***any*** sterile" version of "***any*** product containing budesonide", far beyond the products at issue that Apotex has previously asserted to be the only products relevant in this case. AstraZeneca does not record the dated information sought by this request in any file or database. Thus, the burden of collecting this information would be significant; it would require AstraZeneca to laboriously search files in dozens of countries at significant expense. This burden is simply not justified by Apotex's untimely and irrelevant interrogatory.

2. Document Request Nos. 43 and 44

These Document Requests request all documents and things concerning the "sterilization requirements for the manufacture and/or sale" or the "labeling and package insert information" for "Preferid®, including the Preferid® product marketed in Scandinavian countries." (D.I. 151 at 30-31.) Apotex has characterized these Document Requests as "relevant to at least Apotex's invalidity contentions." (D.I.

[8] Throughout this letter, emphasis in quotations has been added unless otherwise stated.

152 at 4.) However, Apotex's rote recitation of relevance falls far short of a clear, legally valid explanation of ***how*** these products affect ***Apotex's invalidity contentions in this case***. Tellingly, despite having responsive information concerning Preferid®, Apotex does not mention that product in its contentions at all. And, it cannot be sufficient explanation that Apotex's Document Requests merely "relate[] to a sterile budesonide product" (D.I. 147 at 5.) Preferid® was a topical budesonide cream sold by AstraZeneca outside the United States, briefly and many years ago. Although for a limited time it was identified as "sterile according to Ph.Eur.", information concerning this product, including its method of manufacture and labeling information, has no bearing on this litigation. Preferid® was never marketed in the United States. Moreover, its identification as a sterile product was derived from European standards, not from the criteria of sterility provided in the United States Pharmacopeia, as set forth in the '834 patent claims. Collecting information for these Document Requests would thus require AstraZeneca to conduct burdensome searches in foreign countries looking for documents from many years ago, if those documents even exist at all.

In view of the above, AstraZeneca respectfully requests that the Court dismiss Apotex's motion to compel production of the discovery identified in Apotex's April 7, 2010 letter.

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AstraZeneca's Attorney-Client Privilege Claims Are Justified

On January 15, 2010, counsel for AstraZeneca requested Apotex to return an inadvertently produced document shielded by the attorney-client privilege. (D.I. 152-2.) This document reflects a privileged and confidential communication to James Peel, a former AstraZeneca in-house patent counsel in Sweden, from the AstraZeneca inventors of the '834 patent.[9] Upon receipt of AstraZeneca's letter,

[9] Apotex's arguments impugning AstraZeneca's legitimate claims of attorney-client privilege exemplify a strategy of delay. These issues could easily have been raised ***months*** ago if Apotex had not dragged its feet during discovery. **Indeed, as early as last November, counsel for AstraZeneca proposed a December 2009 exchange of privilege logs with Apotex and Breath**. Ex. C, November 17, 2009 letter from Derek Kato, Esq. to Amy Brody, Esq. and David Aldrich, Esq. Counsel for AstraZeneca made additional inquiries in December 2009 and February 2009 about exchanging privilege logs. In view of this delay, and the general obfuscation in which Apotex has engaged during fact discovery, Apotex's attempt to raise last-minute privilege issues should be denied as untimely.

Apotex was required by the plain language of the Discovery Confidentiality Order to "promptly. . . return" the document. (D.I. 90 at 10.) Yet Apotex held the document back for ***more than two months***. Now, Apotex asks this Court to compel the production of ***more than 90*** AstraZeneca documents.[10] As explained below, it is clear from even a cursory review of the law that Apotex's analysis of the privilege issue is incorrect.

1. U.S. Privilege Law Applies To The Privileged Communications

Apotex suggests that Swedish law controls in assessing whether the AstraZeneca documents identified in its April 7, 2010 letter are privileged. This is wrong. In fact, these documents are properly evaluated under ***U.S.*** privilege law which without doubt protects the documents at issue.

District Courts, including one District Court in this Circuit, have found that privileged communications "touching base" with the United States are properly governed by U.S. discovery rules. *See, e.g.*, *Astra Aktiebolog v. Andrx Pharms.*, 208 F.R.D. 92, 98 (S.D.N.Y. 2002); *Tulip Computers Int'l B.V., v. Dell Computer Corp.*, 210 F.R.D. 100, 104 (D. Del. 2002); *Willemijn Houdstermaatschaapij BV v. Apollo Computer*, 707 F. Supp. 1429, 1445 (D. Del. 1989); *Golden Trade S.r.L. v. Lee Apparel Co.*, 143 F.R.D. 514, 520 (S.D.N.Y. 1992) (listing cases). Federal Courts will grant deference to foreign statutes in certain circumstances, respecting principles of international comity, so long as that foreign law is not contrary to the public policy of the American forum. *See Odone v. Croda Int'l*, 950 F. Supp. 10, 12 (D.D.C. 1997).

Here, the privileged documents identified by Apotex all "touch base" with the United States. More than half of these documents relate to the preparation and prosecution of a United States patent application, from which two of the U.S. patents-in-suit claim priority.[11] For these documents, AstraZeneca's privilege log clearly identifies an attorney from AstraZeneca's U.S. counsel (Fish & Richardson) as either a sender or recipient. Such communications between patent counsel and client are clearly privileged. *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 805 (Fed. Cir. 2000); *Bristol-Myers Co.v. Sigma Chem. Co.*, 7 U.S.P.Q. 2d 1574, 1576 (D. Del. 1988). Courts have found analogous communications between foreign

[10] Apotex identifies the withheld documents at issue by their entry number on AstraZeneca's privilege log. (D.I. 147 at 8, n. 36.)

[11] Doc. Nos. 34-38, 41-43, 50-56, 59-72, 90-97, 99-101, 113-114, 121, 123-126, 156-157, 182, 183, 185, and 186.

in-house counsel and outside American counsel to "touch base" with the United States, and thus to fall within the purview of American privilege rules. *See, e.g.*, *Astra Aktiebolog*, 208 F.R.D. at 99.

The remaining privileged documents identified by Apotex involve either the Swedish priority application for one of the U.S. patents-in-suit,[12] or the Patent Cooperation Treaty ("PCT") application through which that Swedish application was granted priority in the U.S.[13] The PCT provides, among other things, procedures by which applicants may seek patent protection for an invention in multiple countries by filing a single "international" patent application that designates the countries in which protection is sought. There are over 140 signatory countries, including the U.S. It should not be surprising that multinational companies like AstraZeneca routinely seek overseas (particularly in the U.S.) patent protection by filing PCT applications after an initial foreign filing is made.

Courts have found that communications concerning foreign priority applications for U.S. patents sufficiently "touch base" with the United States. These communications are therefore governed by U.S. privilege law, not Swedish law. *See Odone*, 950 F. Supp. at 13-14; *Astra Aktiebolog*, 208 F.R.D. at 99. And, such communications would be privileged regardless of whether the communication at issue involves an attorney or a patent agent because patent agents (foreign or U.S.) perform lawyer-like functions in connection with patent issues. *See Venitron Med. Prods. Inc. v. Baxter Labs., Inc.*, 186 U.S.P.Q. 324, 325-26 (D.N.J. 1975); *Golden Trade S.r.L*,143 F.R.D. at 519.

Even if this Court were to hold that AstraZeneca's privileged documents did not "touch base" with the U.S., American privilege law should still apply. This was the outcome in the *Astra Aktiebolog* case, in which the Southern District of New York examined communications involving, in part, in-house counsel and outside Korean counsel. *Astra Aktiebolog*, 208 F.R.D. at 99. The Court first considered Korean law, noting that no statutory attorney-client privilege existed in Korea. *Id.* at 100-01. The Court then noted that none of the documents at issue in the case would be discoverable in a Korean civil proceeding. *Id.* at 101. In light of these circumstances, the Court declined to find

> that the absence of Korean attorney-client privilege and work product provisions requires this court to order the wholesale

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12 Doc Nos. 6, 8-13, 19-26, 30-32, 118, 127, 128, and 130-132.

13 Doc. Nos. 129, 149-153, 173-176, 187, 194, and 248.

> production of all of the Korean documents in their entirety. To do so would violate principles of comity and would offend the public policy of this forum.

Id. at 102.

> The Court continued:
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> The fact is that vastly different discovery practices, which permit only minimal discovery, are applicable to civil suits conducted in Korea. Indeed, none of the documents at issue here would be discoverable in a Korean civil suit. Under these circumstances, where virtually no disclosure is contemplated, it is hardly surprising that Korea has not developed a substantive law relating to attorney-client privilege and work product that is co-extensive with our own law. . . . ***[T]o apply Korean privilege law, or the lack thereof, in a vacuum – without taking account of the very limited discovery provided in Korean civil cases – would offend the very principles of comity that choice-of-law rules were intended to protect.***
>
> Further, ordering discovery without any protection also offends the public policy of this forum, which promotes full discovery but, at the same time, prevents disclosure of privileged documents. ***If the court were to rule without taking Korea's discovery practices into account, the court would be required to order complete disclosure of all of the Korean documents, many of which would be protected under either the attorney-client privilege or work product doctrine as applied in this jurisdiction.***

Id. (citation omitted.)

The Court concluded that the "application of foreign privilege law . . . would require disclosure of many documents (1) that are protected from disclosure under American law and (2) that would not be discoverable under Korean law." *Id.* Faced with this outcome, the Court instead applied U.S. privilege law, even though the documents at issue did not "touch base" with the U.S.

Thus, even if the Court in this case were to find that AstraZeneca's privileged documents failed to "touch base" with the U.S., and even if there is no statutory

privilege protection in Sweden for in-house counsel, this Court should properly apply U.S. privilege law to those documents to preserve principles of public policy.

2. Apotex Mischaracterizes The Swedish Law Concerning Privilege

Apotex's discussions concerning Swedish privilege law are irrelevant and incomplete. Apotex's letter summarily dismisses as "inapposite" two cases cited in earlier correspondence by AstraZeneca, in which courts recognized a Swedish affidavit on the applicability of attorney-client privilege to in-house attorneys in Sweden as persuasive evidence. *See Santrade Ltd. v. Gen. Elec. Co.*, 150 F.R.D. 539 (E.D.N.C. 1993); *Saxholm AS v. Dynal, Inc.*, 164 F.R.D. 331 (E.D.N.Y. 1996). Both of these cases are consistent with the one case Apotex cited in its response letter to AstraZeneca. *In re Rivastigmine Patent Litig.*, 237 F.R.D. 69 (S.D.N.Y. 2006). Observing that the assumptions and ultimate rulings in *Santrade* may have been appropriate based on the evidence before that tribunal, the *Rivastigmine* Court declined to find privilege only because no evidence of Swedish law had been submitted to it in that case. *In re Rivastigmine,* 237 F.R.D. at 100. Thus, *Santrade*, *Saxholm* and *Rivastigmine* are in accord: declarations are persuasive evidence of Swedish law that courts may consider in their privilege evaluations. Apotex has submitted no such declaration.

At this late stage, with fact discovery over, *Markman* briefing completed and expert discovery about to begin, AstraZeneca respectfully submits that this case should not get sidetracked into collateral briefing over details of Swedish law. However, to the extent that this Court finds that the disputed AstraZeneca documents do not "touch base" with the U.S., AstraZeneca has submitted the Declaration of Peter Sande (the "Sande declaration") as authoritative evidence on matters of Swedish civil and evidentiary law.[14]

As explained in the Sande declaration, whether or not Swedish statutory privilege extends to in-house counsel is not determinative. Sweden is a civil law country in which, absent extraordinary circumstances, the law forbids forced disclosure of any communications or documents reflecting legal advice, or requests for legal advice, between members of an in-house legal department and the parent company.[15] No such circumstances are present in this case. As a result, the documents and information identified by Apotex in its April 7, 2010 letter ***could not be compelled in Sweden*** under that country's laws.[16] And, even though the Swedish prohibitions on forced disclosure are procedural in nature, they are, as discussed

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14 Ex. D, April 16, 2010 Declaration of Peter Sande.
15 Ex. D at ¶ 15.
16 Ex. D at ¶ 18.

previously, relevant for U.S. courts evaluating assertions of privilege. *See Astra Aktiebolog*, 208 F.R.D. at 99-102.

In view of the above, AstraZeneca respectfully requests that the Court deny Apotex's motion to compel the privileged documents identified in Apotex's April 7, 2010 letter.

We look forward to addressing these issues with Your Honor at the status conference on April 29, 2010.

Respectfully submitted,

s/John E. Flaherty

John E. Flaherty

cc: Counsel of Record (via ECF)